New Cardiovascular Surgery Chair at Mayo Clinic in Rochester

Joseph A. Dearani, MD, has been named chair of the Division of Cardiovascular Surgery at Mayo Clinic in Rochester. Dr Dearani is a 1986 graduate of Georgetown University School of Medicine in Washington, DC. He completed postgraduate training at Georgetown, Harvard University, Mayo Clinic in Rochester, and Loma Linda University Medical Center. He joined the Mayo Clinic Division of Cardiovascular Surgery in 1996. He is a professor of surgery and holds joint appointments in the Divisions of Cardiovascular Surgery and Transplantation Surgery. Dr Dearani is board certified by the American Board of Surgery and the American Board of Thoracic Surgery, with subspecialty board certification in Congenital Cardiovascular Surgery.

Dr Dearani has been the director of the thoracic surgery residency training program at Mayo Clinic in Rochester since 2002. His clinical interests include congenital heart disease in infants, children, and adults; hypertrophic obstructive cardiomyopathy; and cardiac transplantation. He has authored more than 200 journal articles on the surgical management of heart disease.

Mayo Clinic Study Finds Physician Involvement Key in Successful Weight Loss

The rising prevalence of obesity in the United States has been linked to an increased risk of cardiovascular disease as well as poor outcomes in obese patients. Central obesity (defined as waist circumference ≥102 cm in men and ≥88 cm in women) in particular has been associated with increased cardiovascular risk. Most patients are unable to lose weight and successfully maintain weight loss. A recent study by cardiologists at Mayo Clinic in Rochester and published in the November 2010 issue of the American Heart Journal revealed that physician diagnosis of obesity was a significant predictor of both attempts and success at weight loss.

In a review of National Health and Nutrition Examination Survey data compiled between 1999 and 2004, demographic, motivational, and clinical factors were examined using multivariable logistic regression. “Most of these patients were aware of the fact that they were overweight and wanted to lose weight,” according to Francisco Lopez-Jimenez, MD, a cardiologist at Mayo Clinic in Rochester and one of the study’s authors. “Identification of weight loss as a specific treatment goal by the patient’s physician was the most important predictor of successful weight loss.”

The study also found that there was poor documentation of implementation of an obesity management plan in obese cardiovascular patients. “The recognized role of obesity in the development of hypertension, diabetes mellitus, and hyperlipidemia makes it imperative for obese patients to lose weight, especially if they already have established coronary artery disease,” Clinicians’ understanding of the cultural, genetic, and personal motivational factors in play in the development of obesity and their role in successful weight loss is incomplete; however, this study underscores the important role of the physician in helping patients identify and achieve weight loss goals.
With the support of generous benefactors, Mayo Clinic in Arizona has established a state-of-the-art simulation facility dedicated to multidisciplinary clinical training and research. Medical simulation creates realistic clinical scenarios in computerized, life-sized patients, where doctors in training can respond in real time to situations commonly encountered in clinical practice without any risk to actual patients.

Traditional training in cardiac catheterization procedures involves only real-life exposure to patients. In an effort to promote excellence and patient safety in physician training while reducing risk to patients, the interventional cardiologists at Mayo Clinic in Arizona have acquired the Samantha endovascular simulator.

“Fellows learn basic cardiac catheterization techniques and face common scenarios before ever touching an actual patient,” says John P. (Jack) Sweeney, MD, director of the cardiac catheterization laboratory at Mayo Clinic in Arizona. Nurses and radiology technologists will update their skill sets and learn new techniques using this system. Orientation of new staff will start with simulation training instead of with patients.

The Samantha endovascular simulator allows fellows to perform routine diagnostic catheterizations, coronary interventions, and peripheral vascular interventions in a simulated environment. The trainee faces various situations and complications that might be encountered in a real-life case. The responses may range from a pharmacologic or mechanical solution to defibrillation for life-threatening arrhythmias. A videotape of the simulated case can be captured and the case reviewed with experts in the field. Constructive criticism and suggestions regarding management allow the trainee to learn in a more relaxed environment before encountering a similar situation in the catheterization laboratory.

This system builds on existing simulation training for emergency medical services personnel addressing cardiovascular conditions, especially ST-elevation myocardial infarction. Through this experience, instances when teamwork has not been optimal can be identified. Simulation training for emergency medical services, emergency department, and cardiac catheterization laboratory staff focusing on teamwork is used to optimize the care of such patients. From a research standpoint, the effects of simulation training on quality and safety metrics will be tracked and quantified.

This effort to optimize the care of patients undergoing invasive cardiac procedures is being led by Dr. Sweeney, F. David Fortuin, MD, and Richard W. Lee, MD, all invasive cardiologists. Dr. Fortuin, who is a codirector of the Multidisciplinary Simulation Center, notes that “simulation training is becoming part of the culture at Mayo Clinic. It is no longer considered an alternative educational technique, but rather an integral part of medical training.”
PREVAIL PROTECT Study Extending Eligibility for Left Atrial Occlusion Devices in Atrial Fibrillation

Because of the long-term disability and mortality associated with stroke, it remains perhaps the most feared medical event for adult patients. In the United States alone, approximately 800,000 strokes occur per year, the majority of which are first occurrences. These strokes are the third leading cause of death and the leading cause of disability in the United States and account for up to $75 billion of health care.

The age-associated incidence of stroke has been well documented, with higher rates in older patients and increased prevalence as the population ages. The majority of strokes (approximately 80%) are either ischemic or thromboembolic. Cardioembolic strokes are associated with the worst long-term outcomes, probably related to the amount of thrombotic material involved.

Atrial fibrillation (AF) is a major risk factor for stroke; patients with this arrhythmia have an approximately 5-fold higher risk of stroke. The relationship between increasing age, the increasing incidence of AF, and the increasing rate of stroke has been well documented. Antithrombotic therapy with warfarin (and more recently dabigatran) has been the cornerstone of stroke prevention in patients with AF, but issues such as bleeding, individual variability in response to drug dosing, and need for laboratory testing have led to its underutilization.

Left atrial appendage occlusion devices are being tested as an alternative to antithrombotic therapy for patients with nonvalvular AF. “The finding that the left atrial appendage is the source of approximately 90% of the thrombus in patients with stroke has been responsible for the great interest in a device strategy,” says David R. Holmes Jr, MD, an interventional cardiologist at Mayo Clinic in Rochester.

To date, a single randomized trial has been completed. Only 1 device was tested in that trial (Watchman; Atritech, Inc, Plymouth, Minnesota). In such a trial, the patient population included, the trial performance, and the primary endpoints are of crucial importance. The Embolic Protection in Patients With Atrial Fibrillation (PROTECT AF) trial randomized patients with nonvalvular AF at risk for stroke (CHADS2 [congestive heart failure, hypertension, age >75 years, diabetes mellitus, and prior stroke or transient ischemic attack] score ≥1) either to device implantation or to conventional therapy with warfarin. To qualify for enrollment in the study, patients had to be able to receive warfarin; those unable to receive warfarin or in whom warfarin was contraindicated were not eligible. In the device group, patients were treated with warfarin for 45 days on the basis of the assumption that by the end of 45 days, the device would have become fully endothelialized, after which warfarin was discontinued. Aspirin and clopidogrel were administered for 6 months and then aspirin alone.

The efficacy endpoint was a composite of all-cause death, stroke or thromboembolism, and major bleeding. The safety endpoints are compared in the Table. The device was noninferior to warfarin therapy for the primary efficacy endpoint. There was, however, an early safety hazard

<table>
<thead>
<tr>
<th>Event</th>
<th>PROTECT AF</th>
<th>CAP</th>
<th>P</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant success, No./total (%)</td>
<td>485/542</td>
<td>239/271</td>
<td>246/271</td>
<td>437/460</td>
</tr>
<tr>
<td>Procedure/device-related safety adverse event within 7 d, No./total (%)</td>
<td>42/542 (7.7)</td>
<td>27/271 (10.0)</td>
<td>15/271 (5.5)</td>
<td>17/460 (3.7)</td>
</tr>
<tr>
<td>Procedure-related stroke, No./total (%)</td>
<td>5/542 (0.9)</td>
<td>3/271 (1.1)</td>
<td>2/271 (0.7)</td>
<td>0/460 (0)</td>
</tr>
<tr>
<td>Serious pericardial effusion within 7 d, No./total (%)</td>
<td>27/542 (5.0)</td>
<td>17/271 (6.3)</td>
<td>10/271 (3.7)</td>
<td>10/460 (2.2)</td>
</tr>
</tbody>
</table>

b From tests comparing the PROTECT AF cohort with the CAP cohort.
c From tests for differences across 3 groups (early PROTECT AF, late PROTECT AF, and CAP). By definition, early and late refer to the first half and second half of the entire cohort of patients enrolled in PROTECT AF.
in the device limb, with increased perioperative events, mainly pericardial effusion. In addition, a small number of perioperative strokes occurred, usually the result of air embolism during the procedure. Subsequent to completion of the study, a continued access protocol was initiated, which documented continued efficacy of the device and a reduction in procedural complications, the latter of which was achieved by improved operator experience and implantation techniques and equipment design modifications.

“The PROTECT AF trial substantiated the hypothesis that the left atrial appendage was responsible for the majority of strokes in patients with nonvalvular AF,” says Dr Holmes. It also documented that device placement is noninferior to chronic warfarin therapy for stroke prevention, systemic embolization, and mortality. As could be expected, the trial also identified the fact that invasive procedures carry with them procedural risks which, while infrequent, account for a potential early safety hazard. The risk-benefit ratio of this early safety hazard with the device needs to be compared with the long-term potential for adverse effects with antithrombotic therapy in the consideration of specific therapeutic strategies for each individual patient.

Another trial (PREVAIL) with a similar design using this specific device has been initiated. This multicenter, randomized trial will involve 50 investigational sites and will enroll up to 475 patients. Patients must have nonvalvular AF, be eligible for warfarin therapy, and have a CHADS2 score of 2 or more. Randomization will be 2:1 to receive the device vs warfarin only therapy. The primary endpoint is a composite of hemorrhagic stroke, ischemic stroke, systemic embolism, and cardiovascular or unexplained death. This follow-on trial will have several aims:

- Confirmation of the improved safety results seen in the continued access protocol
- Documentation of the safety and efficacy results when new centers and implanting physicians are added

**Confirmation of Continued Efficacy**

The documentation of efficacy of left atrial appendage occlusion for stroke prevention in patients with nonvalvular AF has sparked great interest in the field, and several companies are involved in the development and testing of devices. Currently, 2 percutaneous devices have European CE mark approval and are being used clinically, and more are expected. These devices have the potential to dramatically improve patient care, especially in patients not eligible for long-term antithrombotic therapy.

For additional information about enrolling patients in PREVAIL, contact Dr Holmes or study coordinator Linda Tesmer, RN, at 507-255-8354.

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**RECOGNITION**

William E. Boden, MD, professor of medicine at the University of Buffalo, presented the fifth annual Gerald T. Gau lecture. Dr Boden (left) is pictured with Dr Gau.

Robert D. Simari, MD, is chair of the National Heart, Lung, and Blood Institute Cardiovascular Cell Therapy Research Network (CCTRN). This network includes 5 major regional centers throughout the United States and 8 satellite treatment sites and is charged with performing early-stage clinical trials in heart disease using cell-based therapeutics. Current clinical trials all use autologous bone marrow mononuclear cells to be delivered into the heart in patients with acute, subacute, or chronic myocardial infarction. Dr Simari is also currently the Dean of Clinical and Translational Research and the Associate Director of the Center for Translational Scientific Activities at Mayo Clinic in Rochester and Vice Chair of the Division of Cardiovascular Diseases.
Using Registries to Assess Clinical Practice and Improve Patient Care

An article published in the January 5, 2011, issue of *JAMA*, “Non–Evidence-Based ICD Implantations in the United States,” stirred widespread comment in the medical and general press. The research assessed patients receiving an implantable cardioverter-defibrillator (ICD) for primary prevention of sudden cardiac death. The patients were entered in the National Cardiovascular Data Registry (NCDR) ICD Registry between January 1, 2006, and June 30, 2009, to determine if they received the ICD on the basis of established practice guidelines. The study reported that 22.5% of patients did not meet evidence-based criteria for implantation. It is important to understand how the ICD Registry was developed and how this article highlights the emerging practice of measuring and public reporting of physician and hospital outcomes, with a goal of improving the quality of medical care.

Developing the ICD Registry

The registry was developed through a partnership of the Heart Rhythm Society (HRS) and the American College of Cardiology Foundation (ACCF) using the expertise of the NCDR. The registry was mandated by the Center for Medicare & Medicaid Services (CMS) in the National Medicare Coverage Decision to expand ICD coverage on the basis of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) results. The National Medicare Coverage Decision described a policy termed Coverage With Evidence Development that allowed expanded coverage as long as patients were entered into a registry to track outcomes. The registry began collecting data in April 2006 and now includes all 1,489 hospitals in the United States performing ICD procedures and has collected data on more than 750,000 ICD placements. “The CMS directive is to enter data on Medicare beneficiaries receiving an ICD for the primary prevention of sudden cardiac death, but to their credit, 84% of hospitals have chosen to submit data on all device recipients, regardless of age or device indication,” according to Stephen C. Hammill, MD, a cardiologist at Mayo Clinic in Rochester and an author of the *JAMA* paper. Approximately 95% of all ICD procedures in the United States are entered into the ICD Registry.

This extensive reporting provides the most comprehensive characterization of contemporary ICD practice and permits meaningful comparison with published randomized controlled trials such as SCD-HeFT and the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II). The Table lists the characteristics of patients enrolled in SCD-HeFT and MADIT-II compared with patients in the ICD Registry, indicating that the registry patients are older, with a greater proportion of women and patients with atrial fibrillation, hypertension, and diabetes. Thus, the ICD Registry better depicts the types of patients receiving ICDs in the real world, in contrast to randomized controlled trials where patient entry was restricted. The registry has made substantial progress toward several predefined goals:

- **Reveal the degree to which clinicians are managing ICD therapy in accordance with evidence-based medicine**
- **Enable clinicians to compare their in-hospital outcomes with those of other physicians**
- **Provide insights for clinical investigation**
- **Highlight the ICDs’ performance outside clinical trial constraints**
- **Provide a detailed view of the morbidity, mortality, and resource utilization associated with ICD therapy**
- **Assess local hospital needs for quality assurance and quality improvement**
- **Serve as a hospital and physician response to “performance measures” initiatives**

“A key aspect of the registry is to improve quality performance at hospitals implanting ICDs, which is achieved, in part, through benchmarking reports provided to hospitals on a quarterly basis, detailing the outcome for all data elements and summarizing performance metrics,” says Dr Hammill. Each hospital is compared with hospitals of similar procedure volume and the national aggregate. Reviews of the annual data reports published by the ICD Registry Steering Committee since 2007 have demonstrated a gradual trend in improvement of outcomes during the first 4 years of registry activity. The total procedure-related adverse events have

| Table. Characteristics of Patients Entered Into Randomized Controlled Trials and the ICD Registry |
|-----------------|-----------------|-----------------|-----------------|
| Characteristic  | MADIT-II (%)    | SCD-HeFT (%)    | ICD Registry (%) |
| Age, y          | 65.5            | 60.1            | 68.1            |
| Male sex, %     | 85              | 76              | 74              |
| Diabetes, %     | 35              | 30              | 37              |
| Atrial fibrillation, % | 9       | 16              | 31              |
| Hypertension, % | 53              | 56              | 75              |

*Pediatric Cardiology †Mayo Health System
decreased from 3.77% in 2006 to 2.87% in 2009. The ICD Registry is part of the NCDR program, which assesses outcomes in multiple different areas of cardiovascular disease, including cardiac catheterization and percutaneous intervention, carotid artery stenting, and outpatient cardiovascular practice. Data from the ICD Registry have been used in several important publications, providing information on patients receiving ICDs that was not available through the randomized controlled trials including:

- Understanding the application of ICD therapy in the general population
- Gender differences
- Procedure-related adverse events
- Association of physician certification to outcomes and appropriate use of cardiac resynchronization therapy with defibrillator (CRT-D)
- Racial and ethnic differences in CRT-D use
- ICD outcomes in patients with end-stage renal disease
- The relationship between hospital procedure volume and complications of ICD procedures
- The prevalence and predictors of off-label use of CRT-D

**Brief Review of the JAMA Article**

The *JAMA* publication reported that 25,145 of 111,707 ICD placements (22.5%) were non–evidence-based and were associated with a significantly higher risk of in-hospital death and procedure-related complications. Patients were classified as receiving a non–evidence-based implant if they had a myocardial infarction within 40 days prior to ICD placement; coronary revascularization within 3 months prior to ICD placement; New York Heart Association (NYHA) class IV symptoms; or newly diagnosed heart failure at the time of ICD placement. National guidelines developed by the ACCF, American Heart Association, and HRS have described implantation criteria that were developed on the basis of results of randomized controlled trials. In addition, CMS will not reimburse for ICDs placed in the patient groups listed. Of all the patients who received ICDs, 8.3% were implanted within 40 days of myocardial infarction, 0.73% within 3 months of coronary revascularization, 2.7% in patients with NYHA class IV symptoms, and 14.0% in patients with newly diagnosed heart failure. The ICD Registry data form asks if the patient has a history of congestive heart failure and, if so, was it “within the past 3 months, 3-9 months, greater than 9 months.” This is in the background of the guidelines recommending patients be on maximal medical therapy before receiving the ICD, and it is assumed to be unlikely that maximal medical therapy can be achieved in patients with symptomatic congestive heart failure with less than 3 months of treatment. “This study and others documented that the rate of non–evidence-based implants was significantly lower for electrophysiologists, who have been shown in prior publications to have fewer complications and more appropriate device selection than other physicians performing the procedure,” says Dr Hammill.

It is important to note that many patients appropriately receive ICDs outside guidelines on the basis of the physician’s clinical judgment and the patient’s presentation. This includes patients who have an established cardiomyopathy and present to the hospital with a small “troponin leak” subsequently coded as a myocardial infarction, although the acute event was not the cause of the cardiomyopathy which preexisted the small myocardial infarction. In addition, patients may require coro-
nary revascularization and have either a preexisting cardiomyopathy or an indication for a permanent pacemaker. In such patients, it may be elected to place the ICD because of their increased risk of sudden death and need for a pacing device.

Public Reporting of Outcomes

CMS and other payers are increasingly interested in reporting valid measures of patient outcomes, and this reporting requirement has been put into law by the US Congress. Unfortunately, administrative databases developed by payers to assess provider outcomes have several limitations:

- Data definitions are often imprecise
- Final coding may not be supported by the clinical record in a substantial proportion of cases
- It is difficult to distinguish comorbid conditions from complications
- Important clinical risk data such as ejection fraction and NYHA symptom classification are not available

Prospective clinical registries maintained by professional societies, such as the ICD Registry, eliminate the inherent deficiencies of administrative data. While the clinical NCDR registries are more detailed and accurate than administrative data, they are limited by the lack of long-term follow-up. Obtaining reliable follow-up information using chart level data or subsequent patient contact is too costly and resource intensive to collect in a representative national sample as large as that included in the ICD Registry. A hybrid approach being used to develop reliable performance measures combines NCDR clinical data with Medicare Claims Data for follow-up, thus capitalizing on the strengths of both data resources. CMS is working through the National Quality Forum (NQF) and professional societies, including HRS and ACCF, to develop hospital and physician performance measures that will be publicly reported. One such performance measure to assess outcomes following ICD placement using data from the ICD Registry and Medicare Claims Data has been approved by the NQF. The initial analysis using this performance measure identified the median complication rate for a hospital was 7%, with the lowest decile being 4% and the highest decile 13%. This wide range of complications provides an opportunity for improvement by moving hospitals with the highest rate of complications closer to the median and moving the median closer to the lowest decile group.

The recent JAMA article similarly showed a wide variation, with some hospitals implanting only 5% of ICDs outside guidelines and other hospitals implants 50% of ICDs outside guidelines (Figure). Ralph Brindis, MD, MPH, president of the ACCF, stated that “when we see that level of variation, there is no way even a skeptic could say that we don’t have room for improvement in the way that we apply ICD technology.” Although not addressed in the JAMA article, a major clinical problem is that approximately 50% of patients who meet guideline indications for ICDs do not receive the device. “This suggests that physicians are not following practice guidelines and failing to refer many patients who would benefit from this life-saving therapy,” says Dr Hammill.

The federal government is developing incentive programs for adoption of electronic medical record technology that may provide physicians with the ability to do clinical decision making and share decision responsibilities with their patients, thereby reducing the guesswork and improving the practice of evidence-based medicine. Cardiology has led the medical profession in developing practice guidelines based on well-designed randomized controlled trials; these guidelines are used to aid clinicians in practicing evidence-based medicine. Registries then demonstrate to physicians how the guidelines are being applied and evidence-based medicine is being practiced in the community.

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Figure. Rates of non–evidence-based implantable cardioverter-defibrillators across sites. Adapted with permission from Al-Khatib et al, JAMA 2011;305:43-9.
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16th Annual Scientific Session of the American Society of Nuclear Cardiology
Sep 8-11, 2011, Denver, CO
Web: www.asnc.org

RECOGNITION

Veronique Roger, MD, MPH, a consultant in the Division of Cardiovascular Diseases at Mayo Clinic in Rochester, has been named director of the Mayo Clinic Center for the Science of Health Care Delivery. The center will further the scientific study and application of innovative processes to transform and improve the value of health care delivery. Dr Roger has also been elected to the Mayo Clinic Board of Governors.

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